

Title: Patient reported outcome measure for early postoperative recovery following lower limb arthroplasty: A systematic review.

Abstract

Background: Lower limb arthroplasty is an effective surgical treatment option for patients with moderate to severe arthritis who have not responded to medical management[1]. However, surgical interventions can lead to postoperative consequences such as limited mobility, pain and infection. Consequently, improving postoperative recovery holds significant benefits for patients, health care professionals and health care payers. The purpose of this review is to determine if any recovery tools exist that can effectively measure early postoperative recovery after hip or knee arthroplasty.

Methods: The following databases were searched; PubMed (Ovid), EMBASE (Ovid), Medline (Ovid), Web of Science (ISI Web of Knowledge), PsycINFO, Applied Social Sciences Index and Abstracts (ASSIA), Cochrane library and SCOPUS. We restricted our search to English language papers, and adult respondents. Data were extracted by two independent reviewers using a pro-forma spreadsheet and existing quality criteria were applied.

Results: Our literature search identified 23 articles relating to development, assessment and validation of 15 tools. Not all instruments demonstrated the same levels of quality. None of the tools found were specific to both the orthopaedic arthroplasty population and early recovery time periods.

Conclusion: At the present time, there are no fully validated tools to assess early postoperative recovery during the first week following lower limb arthroplasty. A brief, easy-

26 to-complete, reliable patient-reported tool could be of great use. It could not only aid in
27 assessment of recovery but could also evaluate the efficacy of perioperative interventions
28 such as drugs or surgical technique and provide a foundation for evidence-based care.

29

30 Key words: Assessment; postoperative; quality of recovery; scores.

31

32

Introduction: Optimal patient recovery following surgery is critical to improving patient outcomes. Many factors contribute to patient recovery including: motivations , pre-morbid health status, prior operative and anaesthetic experience, type of surgery, analgesia, as well as expectations from surgery [2]. Traditionally, patient recovery has been assessed by the surgeon and allied health care professionals using pain scores and analgesic consumption together with objective measurements including time to achieve set rehabilitation goals, such as knee flexion greater than 90° or hospital discharge [3]. Whilst these objective measurements assess a patient's recovery from the physiological perspective they fail to assess many of the factors known to influence self-reported outcomes. Due to the limitations of objective measurements in assessing patient outcomes, interest has shifted towards the use of patient-reported outcome measures (PROMs) for assessment of surgical interventions [4]. These focus on patient self-reported functioning and well-being [5]. Their use is instrumental in assisting clinicians and policy makers to take important strides towards optimising the provision of care through refining modifiable factors such as indications for surgery, implant selection and surgical technique.

In orthopaedic surgery, whilst PROMs are routinely used to assess the functional outcomes of surgery at six months and beyond, their use before this time point, and in particular the immediate post-operative period is rare. Despite this, the ability to measure the multiple facets of patient recovery from their own perspective at this early time point is critical to improving patient care. From the patient perspective, improving recovery will enhance patient experience and satisfaction. From the surgical perspective, it has been demonstrated that improved perioperative patient recovery is associated with improved short and long term patient outcomes. From the healthcare payer perspective, in the context of increasing patient numbers, finite resources and change in patient expectations, optimising patient recovery and reducing length of stay (LOS) is more important than ever [6, 7].

Such are the benefits to improving the quality of patient recovery that Enhanced Recovery Programmes (ERPs) have been introduced across a wide range of surgical interventions [6]. However, there remains a lack of consensus as to what represents the gold standard or indeed which components are critical to enhancing recovery. This has led to a wide range of different ERPs being used both across different specialties and also within specialties themselves. One reason behind the lack of consensus may be the inability of current methods to assess patient recovery during the early postoperative period. This argument is supported by the findings from a recent audit of UK ERPs for lower limb arthroplasty that demonstrated that patient education was included in over three-quarters of ERPs despite strong evidence that it does not influence standard measures of recovery (LOS) [8]. In addition the lack of an appropriate measure to assess recovery may be why compliance to local ERPs was as low as 40% in some centres.

The aim of this review is to determine which recovery tools can effectively measure early postoperative recovery after hip or knee arthroplasty.

Materials and methods

Eligibility criteria: The number of early recovery tools specifically related to orthopaedic patients was anticipated to be small; therefore a systematic review of *all* recovery tools in *all* postoperative populations was carried out to assess whether they could be applied to an orthopaedic population. Studies that assessed and/or validated specific postoperative recovery tools were included in the review. Studies were selected with no time restriction, through the most recent search date of January 13th 2016. The search was restricted to English language papers and adult respondents.

Inclusion criteria:

- 81 1. Validated postoperative outcome measurements at one week or less after surgery
- 82 2. Surgical studies
- 83 3. English language
- 84 4. Over 18 years of age

85 Studies were not restricted by sample size or by length of follow up. There were no exclusion
86 criteria based on the publication status.

87 **Information sources:** Electronic databases (PubMed (Ovid), EMBASE (Ovid), Medline
88 (Ovid), Web of Science (ISI Web of Knowledge), PsycINFO, Applied Social Sciences Index
89 and Abstracts (ASSIA), The Cochrane library and SCOPUS) were searched from their
90 inception until January 13th 2016 for prospective studies reporting the development,
91 validation and use of post-surgical quality of recovery tools. Searches were tailored to
92 individual databases with the search strategy for MEDLINE shown **below**.

93 1. postoperative.mp.

94 2. recovery.mp.

95 3. quality.mp.

96 4. 1. AND 2. AND 3.

97 5. assessment*.mp. OR score*.mp. OR scale*.mp.

98 6. 4. AND 5.

99 The search strategy included the use of text words and MESH terms. In addition, reference
100 lists of reviews and retrieved articles were assessed for further studies and registers of
101 controlled clinical trials (metaRegister of controlled trials (mRCT) (www.controlled-

trials.com/mrct), clinicaltrials.gov (www.clinicaltrials.gov) and the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (<http://apps.who.int/trialsearch/>) were searched for ongoing trials. A summary of the search results is presented as a PRISMA flowchart [9] **Figure 1**.

Data collection: The full texts of eligible studies were retrieved and data extracted into an electronic database. The search, appraisal and extraction processes were performed in duplicate by two independent reviewers (LS and TH). Items recorded included author; year; country; patient demographics (sex and age); surgical procedure; recovery tool; number of patients; method and timing of administration; outcomes; findings and validation methodology.

The data were extracted and appraised in line with established criteria [10].

Quality Criteria:

For any assessment tool to be effective, one needs to establish its quality, appropriateness, acceptability, precision, reliability, validity and responsiveness to change over time [10]. The tools identified were assessed against these recognised criteria.

Results

Study Characteristics: 23 studies, relating to 15 unique recovery tools were found (**Table 1**). The 15 tools found were:

9-item Quality of Recovery from Anesthesia (QoR 9) survey [11-14];

15-item Quality of Recovery from Anesthesia (QoR 15) Survey [15];

124 40-item Quality of Recovery from Anesthesia (QoR 40) Survey [16-19];
 125 Postoperative Recovery Profile (PRP) [20, 21];
 126 15-item questionnaire (FS-15) [22];
 127 Postoperative Quality-of-life Metric (PQL) [23, 24];
 128 24-hour Functional Ability Questionnaire (24hFAQ) [25];
 129 Convalescence and Recovery Evaluation (CARE) [26];
 130 Post-discharge surgical recovery scale (PSR) [27];
 131 Post-anesthesia short-term quality of life (PASQOL) [28];
 132 Surgical Recovery Scale (SRS) [29];
 133 Postoperative Quality of Recovery Scale (PQRS) [30];
 134 General Symptom Distress Scale (GSDS)/Functional Status Questionnaire (FSQ) [31];
 135 Surgical Recovery Index (SRI) [32], and
 136 Functional Recovery Index (FRI) [33].
 137 Timing of the instruments began from the preoperative period through to one year post-
 138 operatively. Most studies included at least one preoperative baseline evaluation, where others
 139 (PRP, FS-15, 24hFAQ, PASQOL and SRI) were only assessed in the postoperative phase.
 140 Important considerations in the timing of administration of questions in very early recovery
 141 are the effects of pain, anaesthetics and cognitive concerns in the elderly population [34].
 142 Timing is shown in **Table 2**.
 143 **Table 3** shows quality measurement criteria.

Appropriateness: Table 4 demonstrates domains that are covered by the instruments. None of the instruments were designed specifically for an orthopaedic population; with most being developed and validated in a mixed general surgical population.

Acceptability to patients and feasibility: The mean time taken to complete ranged from two minutes to ten minutes for seven of the tools. Time taken was not given for FS-15, PQL, CARE, PASQOL, SRS, PQRS, SFQ or SRI. Most instruments rated highly on acceptability with completion rates of over 77%. The lowest ranking instrument, with a completion rate of 50%, was the SRI. The next lowest instruments with 74% were PQL and PASQOL.

Precision: The majority of studies utilize closed questions and Likert scale items with 3-point to 5-point or response categories. Some instruments use a visual analogue scale (VAS) as a means to elicit their response. The authors of the FS15 did not provide any information regarding the type of questions in their tool. Ceiling and floor effects also demonstrate a tool's precision[35]. Instruments reporting ceiling and floor effects included CARE, PSR, QoR-9 and SRI.

Reliability: All studies except the FS-15, PQRS and PASQOL presented Cronbach's alpha. Of the studies reporting Cronbach's alpha, all but GSDS FSQ and 24hFAQ were within the recommended range. CARE was at the lower end of recommended ranges with 0.7 and QoR9 ranged from 0.57-0.90. Studies reporting reliability are QoR9, QoR15, QoR40, CARE and FRI. The PRP [20] utilized a Swedish statistical programme for analysis [36, 37]. These did not give traditional ICC, but reported reliability of 80-100% using their own statistical methodology. The PSR reported an intra-observer testing for reliability. Sample sizes for instrument populations are listed individually in Table 1 and combined in Table 2.

Validity: Construct and content validity were demonstrated throughout the tools with the exception of FS-15 and GSDS FSQ. Unfortunately, as no gold standard exists in terms

recovery instrument, none of the included studies were able to demonstrate criterion validity [12].

Responsiveness: The timing of the test administration itself plays a pivotal part in evaluation and is demonstrated in **Table 2**. Standardised response mean (SRM) and effect size (EF) were reported from the QoR-9, QoR-15 and QoR-40. Minimum reported change (MIC) was utilized in the SRS. Analysis of scoring across different timing of testing was used for both PRP and PQRS instruments. In assessing postoperative recovery, it is important to establish a preoperative baseline to determine how individual patients are improving in the postoperative phase. Although many of the instruments included made an evaluation at baseline, four did not (PRP, FS-15, 24hFAQ, PASQOL and SRI).

Discussion: The most important finding from this review is that whilst we identified 15 instruments to assess postoperative recovery, none were found to fulfil all quality criteria and be valid for assessing early postoperative recovery in the hip or knee arthroplasty population. Whilst the QoR-40 met all requirements for a recovery tool, analysis revealed that only the physical domain was valid in assessing quality of life in the knee arthroplasty population, and only then in the first month, not first few days following surgery [18, 38].

This review indicates that there is no ideal postoperative recovery specific measure for hip and knee arthroplasty. One of the reasons for this is that of the 15 patient-reported instruments identified only seven were developed in populations which involved orthopaedic patients (FRI; PQRS; PRP; PSR; QoR-9, QoR-15 and QoR-40). However, in these seven studies, only 1526 out of a total of 10,281 patients (less than 15%) were orthopaedic patients thus limiting the applicability of these instruments. It is likely that recovery factors important to patients undergoing orthopaedic surgery are significantly different to recovery factors in patients undergoing other types of surgery. For example, bowel function and gastrointestinal

recovery are highly ranked concerns in the general surgical population whereas pain, mobility and personal hygiene were found to be the top ranking outcome concerns in the orthopaedic patient during PRP testing and analysis [39].

Furthermore, patient recovery is likely influenced by factors outside of the direct physiological effects of the surgery itself, including the motivations and psychological preparation for surgery. The QoR-40, which was initially developed for use in a cardiac surgery population, has been found to have potential application at one month in the physical independence domain, but not in early recovery [18]. The psychological domain however, which may be related to differences in motivations and often urgent psychological preparation for, cardiac surgery compared to joint arthroplasty was found to be not valid.

Reviewing the seven studies that included orthopaedic patients in more detail revealed that only three contained arthroplasty patients (PQRS; PRP and QoR-40) with the remainder involving arthroscopic surgery, trauma or non-specified orthopaedic cases. From the data available it was not possible to explore the recovery profiles of patients undergoing unplanned surgery for trauma and those undergoing planned surgery to determine if they shared similar recovery profiles, and as such, if they could be assessed using a single recovery tool. However, the evidence suggested that recovery tools are able to differentiate between different types of surgery on the same joint with significantly worse PQRS scores, particularly cognitive function, nociception, emotional recovery and daily activities, following knee arthroplasty compared to knee arthroscopy [30].

Despite acknowledging that recovery is multi-factorial the way that we assess patient recovery has not substantially changed in recent years. Reviewing published randomised controlled trials of ERPs in lower limb arthroplasty reveals that they all use pain score as the primary outcome, with opiate usage and length of stay typically used as secondary outcomes.

The use of pain scores to assess patient recovery has significant disadvantages, most notably that a low pain score can be achieved by administering high dose of pain relief, including opioids. Whilst effective for pain, these can result in significant side effects such as nausea and vomiting in over half of patients. Likewise opiate utilisation is a poor proxy for pain as it is known that once a patient has required opiates for breakthrough pain they are significantly more likely to be given opiates, independent of their pain score. Finally length of stay is known to be affected by many confounding factors, and does not assess recovery from the patient's perspective.

Evaluating the quality of these health measurement instruments is critical in perioperative care as they can influence and affect the interventions our patients receive [38]. The absence of a validated patient reported recovery instrument to measure early recovery following hip or knee arthroplasty limits the ability to assess which interventions represent the gold standard treatment to optimise recovery in this population. From the evidence presented it would therefore seem appropriate that a tool to assess recovery following lower limb arthroplasty is developed in an orthopaedic population. Such a tool has potential to be used to evaluate the provision of care and assess different treatment interventions, be they physical, pharmacological or psychological. This would allow us to improve care pathways for our patients and lead to clinical patient centred advancement.

Some exciting work on PROMs is being carried out through the National Institute of Health (NIH) in the United States. The patient-reported outcomes measurement information system (PROMIS) instruments, show potential for many patient populations including those with Musculoskeletal disease [40].

There are certain limitations to this review, in particular, an absolute discussion on quality of recovery is complex because to date no gold standard exists in terms of assessment or

definition of recovery [12]. Additionally, we only included studies carried out and reported in English; therefore some important work in other languages may have been missed. Finally, the studies were performed in different population groups, often with small sample size, and with differing methodologies. As such the data obtained is heterogeneous in nature limiting the interpretations that can be made.

Conclusions: Although traditional recovery indicators are important end points for assessing outcomes and patient safety, they provide only limited insight on the impact of surgery on patient-assessed functioning and well-being. However, at the time of writing, there is no validated PROM for early postoperative recovery following lower limb arthroplasty. This significantly limits research in this area. At present there is also a lack of evidence reporting patients' experience and outcomes of ERP's. Developments in the ERP pathway are driven towards improving measurable outcomes such as length of stay which do not directly represent patient experience.

Future work: To improve patient care it is essential that a validated patient reported outcome measure for recovery following lower limb arthroplasty is developed. We have just received ethical approval to begin work on an early postoperative recovery PROM in the arthroplasty patient population. This work will identify issues and needs in the immediate postoperative phase. It will be developed in an appropriate arthroplasty population. Patient themes will be identified and rationalised. Testing of these items in arthroplasty patients will be used to create this early recovery PROM. Ceiling/floor effect items will be removed and we will then validate the PROM in an independent cohort. It is anticipated that this new tool could be used as a conduit with existing longer term PROMs to allow continuity of postoperative arthroplasty patient recovery and outcomes.

Source of Funding: There was no external source of funding for the study.

265 **Conflict of Interest:** The authors have no conflict of interests and were not involved in the
266 development of any tools discussed in this review.

267

References

1. NationalJointRegistry. *Joint replacement statistics*. 2016 08/02/2016]; Available from: <http://www.njrcentre.org.uk/njrcentre/Patients/Jointreplacementstatistics/tabid/99/Default.aspx>.
2. Flanigan, D.C., J.S. Everhart, and A.H. Glassman, *Psychological Factors Affecting Rehabilitation and Outcomes Following Elective Orthopaedic Surgery*. Journal of the American Academy of Orthopaedic Surgeons, 2015. **23**(9): p. 563-570.
3. Halawi, M.J., *Outcome Measures in Total Joint Arthroplasty: Current Status, Challenges, and Future Directions*. Orthopedics, 2015. **38**(8): p. e685-9.
4. Boyce, M.B., J.P. Browne, and J. Greenhalgh, *The experiences of professionals with using information from patient-reported outcome measures to improve the quality of healthcare: a systematic review of qualitative research*. BMJ Quality & Safety, 2014.
5. Wu, C.L. and L.A. Fleisher, *Outcomes research in regional anesthesia and analgesia*. Anesth Analg, 2000. **91**(5): p. 1232-42.
6. Kehlet, H. and D.W. Wilmore, *Evidence-based surgical care and the evolution of fast-track surgery*. Annals of Surgery, 2008. **248**(2): p. 189-198.
7. Lovald, S.T., et al., *Complications, mortality, and costs for outpatient and short-stay total knee arthroplasty patients in comparison to standard-stay patients*. The Journal of arthroplasty, 2014. **29**(3): p. 510-515.
8. McDonald, S., et al. *Preoperative education for hip or knee replacement*. Cochrane Database of Systematic Reviews, 2014. DOI: 10.1002/14651858.CD003526.pub3.
9. Moher, D., et al., *Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement*. PLoS Med, 2009. **6**(7): p. e1000097.
10. Fitzpatrick, R., et al., *Evaluating patient-based outcome measures for use in clinical trials*. Health Technol Assess, 1998. **2**(14): p. i-iv, 1-74.
11. Arnberger, M., et al., *Evaluation of physical and mental recovery status after elective liver resection*. European Journal of Anaesthesiology, 2009. **26**(7): p. 559-565.
12. Myles, P.S., et al., *Development and psychometric testing of a quality of recovery score after general anesthesia and surgery in adults*. Anesthesia and Analgesia, 1999. **88**(1): p. 83-90.
13. Myles, P.S., et al., *Measurement of quality of recovery in 5672 patients after anaesthesia and surgery*. Anaesthesia and Intensive Care, 2000. **28**(3): p. 276-280.
14. Wu, C.L., et al., *Correlation of postoperative pain to quality of recovery in the immediate postoperative period*. Regional Anesthesia and Pain Medicine, 2005. **30**(6): p. 516-522.
15. Stark, P.A., P.S. Myles, and J.A. Burke, *Development and Psychometric Evaluation of a Postoperative Quality of Recovery Score The QoR-15*. Anesthesiology, 2013. **118**(6): p. 1332-1340.
16. Leslie, K., et al., *Quality of Recovery from Anesthesia in Neurosurgical Patients*. Anesthesiology, 2003. **99**(5): p. 1158-1165.
17. Myles, P.S., et al., *Validity and reliability of a postoperative quality of recovery score: the QoR-40*. British Journal of Anaesthesia, 2000. **84**(1): p. 11-5.
18. Poitras, S., P.E. Beaulé, and G.F. Dervin, *Validity of A Short-Term Quality of Life Questionnaire in Patients Undergoing Joint Replacement: The Quality of Recovery-40*. Journal of Arthroplasty, 2012. **27**(9): p. 1604-1608.e1.
19. Shida, D., et al., *The postoperative patient-reported quality of recovery in colorectal cancer patients under enhanced recovery after surgery using QoR-40*. BMC Cancer, 2015.
20. Allvin, R., et al., *Development of a questionnaire to measure patient-reported postoperative recovery: content validity and intra-patient reliability*. Journal of Evaluation in Clinical Practice, 2009. **15**(3): p. 411-419.
21. Allvin, R., et al., *The Postoperative Recovery Profile (PRP) - a multidimensional questionnaire for evaluation of recovery profiles*. Journal of Evaluation in Clinical Practice, 2011. **17**(2): p. 236-243.

22. Bright, A., T. Tan, and L. Briggs, *Validity of a postoperative quality of recovery score after caesarean section: The FS-15*. International Journal of Obstetric Anesthesia, 2009. **18**: p. S22.
23. Delaney, C.P., et al., *Validation of a novel postoperative quality-of-life scoring system*. American Journal of Surgery, 2009. **197**(3): p. 382-385.
24. Keller, D.S., et al., *Construct validation and comparison of a novel postoperative quality-of-life metric and the Short Form-36 in colorectal surgery patients*. Surgery, 2013. **154**(4): p. 690-696.
25. Hogue, S.L., et al., *Assessing a tool to measure patient functional ability after outpatient surgery*. Anesth Analg, 2000. **91**(1): p. 97-106.
26. Hollenbeck, B.K., et al., *Development and validation of the convalescence and recovery evaluation (CARE) for measuring quality of life after surgery*. Qual Life Res, 2008. **17**(6): p. 915-26.
27. Kleinbeck, S.V., *Self-reported at-home postoperative recovery*. Res Nurs Health, 2000. **23**(6): p. 461-72.
28. Oakes, C.L., et al., *Assessment of postanesthesia short-term quality of life: a pilot study*. Aana j, 2002. **70**(4): p. 267-73.
29. Paddison, J.S., et al., *Development and Validation of the Surgical Recovery Scale (SRS)*. Journal of Surgical Research, 2011. **167**(2): p. E85-E91.
30. Royse, C.F., et al., *Knee surgery recovery: Post-operative Quality of Recovery Scale comparison of age and complexity of surgery*. Acta Anaesthesiol Scand, 2014. **58**(6): p. 660-7.
31. Swan, B.A., G. Maislin, and K.B. Traber, *Symptom distress and functional status changes during the first seven days after ambulatory surgery*. Anesth Analg, 1998. **86**(4): p. 739-45.
32. Talamini, M.A., et al., *The surgical recovery index - A novel tool for measuring the advantage of laparoscopic surgery in postoperative recovery*. Surgical Endoscopy and Other Interventional Techniques, 2004. **18**(4): p. 596-600.
33. Wong, J., et al., *Development of the Functional Recovery Index for Ambulatory Surgery and Anesthesia*. Anesthesiology, 2009. **110**(3): p. 596-602.
34. Krenk, L. and L.S. Rasmussen, *Postoperative delirium and postoperative cognitive dysfunction in the elderly - what are the differences?* Minerva Anesthesiol, 2011. **77**(7): p. 742-9.
35. Bindman, A.B., D. Keane, and N. Lurie, *Measuring health changes among severely ill patients: the floor phenomenon*. Medical care, 1990: p. 1142-1152.
36. Svensson, E., *Application of a rank-invariant method to evaluate reliability of ordered categorical assessments*. J Epidemiol Biostat, 1998. **3**(4): p. 403-409.
37. Svensson, E., *Statistical methods for repeated qualitative assessments on scales*. Int J Audiol, 2003. **42 Suppl 1**: p. S13-22.
38. Herrera, F.J., J. Wong, and F. Chung, *A systematic review of postoperative recovery outcomes measurements after ambulatory surgery*. Anesth Analg, 2007. **105**(1): p. 63-9.
39. Aaronson, N., et al., *Assessing health status and quality-of-life instruments: attributes and review criteria*. Qual Life Res, 2002. **11**(3): p. 193-205.
40. Broderick, J.E., et al., *Validity and reliability of patient-reported outcomes measurement information system instruments in osteoarthritis*. Arthritis Care Res (Hoboken), 2013. **65**(10): p. 1625-33.